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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/223,634	12/31/1998	RANDOLPH J. NOELLE	012712 - 652	1304

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	15

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/223634	NOELLE ET AL
	Examiner	Art Unit
	GAMBEL	1644

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on ____.

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) 1, 2, 5-10, 12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) 1, 2, 5-10, 12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Upon a review of the prior art; New Grounds of Rejection have been set forth herein.

2. Claims 1, 2, 5-10 and 12 are pending.
Claims 3, 4 and 11 have been canceled previously.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 2, 5-10 and 12 are rejected under 35 U.S.C. § 102(e) as being anticipated by Noelle et al. (U.S. Patent No. 5,683,693) (see entire document). Noelle et al. teach the use of gp39-specific / CD40L-specific antibodies, including chimeric and humanized antibodies (see columns 5-7, Antibodies) to treat the autoimmune disease diabetes (see entire document, including column 11, Uses of the Methods of Invention). Given the inhibitory properties of such gp39-specific / CD40L-specific antibodies, the prior art teach antibodies having the gp39 binding characteristics of the claimed 89-76 and 24-31 antibodies. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat autoimmune diseases, including diabetes with gp39-specific / CD40L-specific antibodies. A species will anticipate a claim to a genus. See MPEP 2131.02.

6. Claims 1, 2, 5-10 and 12 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lederman et al. (U.S. Patent No. 5,993,816) (see entire document). Lederman et al. teach the use of 5C8-specific / CD40L-specific antibodies, including chimeric and humanized antibodies (see columns 7-8) to treat autoimmune diseases such as rheumatoid arthritis, Myasthenia gravis, SLE, Grave's disease, ITP, and diabetes (see column 11, paragraph 5). Given the inhibitory properties of such 5C8-specific / CD40L-specific antibodies, the prior art teach antibodies having the gp39 binding characteristics of the claimed 89-76 and 24-31 antibodies. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat autoimmune diseases as rheumatoid arthritis, Myasthenia gravis, SLE, Grave's disease, ITP, and diabetes with of 5C8-specific / CD40L-specific antibodies. A species will anticipate a claim to a genus. See MPEP 2131.02.

7. Claims 1-2 are rejected under 35 U.S.C. § 102(e) as being anticipated by Armitage et al. (U.S. Patent No. 6,264,951) (see entire document). Armitage et al. teach the use of CD40 antagonists, including CD40 and CD40/Fc to teat autoimmune diseases, including SLE, rheumatoid arthritis and diabetes, (see entire document, including columns 10-11, overlapping paragraph). Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat autoimmune diseases, including SLE, rheumatoid arthritis and diabetes with CD40 antagonists, including CD40 and CD40/Fc. A species will anticipate a claim to a genus. See MPEP 2131.02.

8. Claims 1, 2, 5-10 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lederman et al. (U.S. Patent No. 5,993,816) AND/OR Armitage et al. (U.S. Patent No. 6,264,951) in view of Schieven (U.S. Patent No. 5,565,491).

Lederman et al. teach the use of 5C8-specific / CD40L-specific antibodies, including chimeric and humanized antibodies (see columns 7-8) to treat autoimmune diseases such as rheumatoid arthritis, Myasthenia gravis, SLE, Grave's disease, ITP, and diabetes (see column 11, paragraph 5).

Armitage et al. teach the use of CD40 antagonists, including CD40 and CD40/Fc to teat autoimmune diseases, including SLE, rheumatoid arthritis and diabetes, (see entire document, including columns 10-11, overlapping paragraph).

Lederman et al. And Armitage et al. differ from the claimed methods by not disclosing certain autoimmune diseases, such as thyroiditis, encompassed by the claimed methods.

Schieven teach the use of phosphotyrosine inhibitors can be used to control proliferation of B cells in which the downregulation of the immune response is desired, as for the treatment of autoimmune diseases such as rheumatoid arthritis, Hashimoto's thyroiditis and SLE as well as other autoimmune diseases (see entire document, including column 17, paragraph 2). Schieven teach that phosphotyrosine inhibitors can be used to inhibit antibody responses mediated by the CD40L gp39 (see column 19, paragraph 2).

Given the teachings of Lederman et al. And Armitage et al. To inhibit several autoimmune diseases with CD40:CD40L antagonists combined with the teachings of Schieven to target B cell responses and antibody responses mediated by CD40L would be useful in treating autoimmune diseases; one of ordinary skill in the art at the time the invention was made would have targeted a number of non-multiple sclerosis autoimmune diseases encompassed by the claimed invention with CD40:CD40L antagonists such as CD40L-specific antibodies or soluble CD40 alone or in combination with standard therapy. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

9. No claim allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
March 11, 2002